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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Rainer Haas et al.	Art Unit:	Not Yet Assigned
Serial No.:	Not Yet Assigned	Examiner:	Not Yet Assigned
Filed:	November 16, 2001	Customer No.:	21559
Title:	Helicobacter Polypeptides and Corresponding Polynucleotide Molecules		

Assistant Commissioner for Patents  
Washington, DC 20231

PRELIMINARY AMENDMENT

Prior to examination of the above-captioned patent application, which is being filed herewith, kindly amend the application as follows.

In the Specification:

Please insert the following after the title on page 1.

Priority Information

This application is a continuation of, and claims priority from, United States patent application Serial No. 08/831,309, filed April 1, 1997.

In the Claims:

Cancel claims 1-38 and add the following new claims 39-58.

39. An isolated polynucleotide that encodes:

(i) a polypeptide comprising an amino acid sequence that is homologous to the amino acid sequence of a *Helicobacter* polypeptide, wherein said amino acid sequence of said *Helicobacter* polypeptide is selected from the group consisting of the amino acid sequences as shown in SEQ ID NO:2 (GHPO 13), SEQ ID NO:4 (GHPO 73), SEQ ID NO:6 (GHPO 90), SEQ ID NO:8 (GHPO 107), SEQ ID NO:10 (GHPO 136), SEQ ID NO:12 (GHPO 191), SEQ ID NO:14 (GHPO 213), SEQ ID NO:16 (GHPO 240), SEQ ID NO:18 (GHPO 408), SEQ ID NO:20 (GHPO 411), SEQ ID NO:22 (GHPO 419), SEQ ID NO:24 (GHPO 431), SEQ ID NO:26 (GHPO 474), SEQ ID NO:28 (GHPO 591), SEQ ID NO:30 (GHPO 596), SEQ ID NO:32 (GHPO 699), SEQ ID NO:34 (GHPO 724), SEQ ID NO:36 (GHPO 730), SEQ ID NO:38 (GHPO 761), SEQ ID NO:40 (GHPO 804), SEQ ID NO:42 (GHPO 805), SEQ ID NO:44 (GHPO 812), SEQ ID NO:46 (GHPO 879), SEQ ID NO:48 (GHPO 888), SEQ ID NO:50 (GHPO 986), SEQ ID NO:52 (GHPO 1056), SEQ ID NO:54 (GHPO 1081), SEQ ID NO:56 (GHPO 1100), SEQ ID NO:58 (GHPO 1140), SEQ ID NO:60 (GHPO 1148), SEQ ID NO:62 (GHPO 1200), SEQ ID NO:64 (GHPO 1212), SEQ ID NO:66 (GHPO 1258), SEQ ID NO:68 (GHPO 1263), SEQ ID NO:70 (GHPO 1273), SEQ ID NO:72 (GHPO 1284), SEQ ID NO:74 (GHPO 1299), SEQ ID NO:76 (GHPO 1327), SEQ ID NO:78 (GHPO

1346), SEQ ID NO:80 (GHPO 1378), SEQ ID NO:82 (GHPO 1412), SEQ ID NO:84 (GHPO 1443), SEQ ID NO:86 (GHPO 1466), SEQ ID NO:88 (GHPO 1476), SEQ ID NO:90 (GHPO 1536), SEQ ID NO:92 (GHPO 1559), SEQ ID NO:94 (GHPO 427), SEQ ID NO:96 (GHPO 1045), and SEQ ID NO:98 (GHPO 1262); or

(ii) a derivative of said polypeptide encoded by said polynucleotide.

40. The isolated polynucleotide of claim 39, wherein the polynucleotide is a DNA molecule.

41. The isolated polynucleotide of claim 39, which is a DNA molecule that can be amplified by polymerase chain reaction from a *Helicobacter* genome, using either:

- A 5' oligonucleotide primer having a sequence as shown in SEQ ID NO:101 and a 3' oligonucleotide primer having a sequence in SEQ ID NO:102;
- A 5' oligonucleotide primer having a sequence as shown in SEQ ID NO:103 and a 3' oligonucleotide primer having a sequence in SEQ ID NO:104;
- A 5' oligonucleotide primer having a sequence as shown in SEQ ID NO:105 and a 3' oligonucleotide primer having a sequence in SEQ ID NO:106;
- A 5' oligonucleotide primer having a sequence as shown in SEQ ID NO:107 and a 3' oligonucleotide primer having a sequence in SEQ ID NO:108;
- A 5' oligonucleotide primer having a sequence as shown in SEQ ID NO:109 and

a 3' oligonucleotide primer having a sequence in SEQ ID NO:110; or

- A 5' oligonucleotide primer having a sequence as shown in SEQ ID NO:111 and  
a 3' oligonucleotide primer having a sequence in SEQ ID NO:112.

42. The isolated DNA molecule of claim 39, wherein said *Helicobacter* is  
*Helicobacter pylori*.

43. A compound, in a substantially purified form, that is the mature form or a  
derivative of a polypeptide comprising an amino acid sequence that is homologous to a  
*Helicobacter* amino acid sequence that is selected from the group consisting of the amino  
acid sequences as shown in SEQ ID NO:2 (GHPO 13), SEQ ID NO:4 (GHPO 73), SEQ  
ID NO:6 (GHPO 90), SEQ ID NO:8 (GHPO 107), SEQ ID NO:10 (GHPO 136), SEQ ID  
NO:12 (GHPO 191), SEQ ID NO:14 (GHPO 213), SEQ ID NO:16 (GHPO 240), SEQ  
ID NO:18 (GHPO 408), SEQ ID NO:20 (GHPO 411), SEQ ID NO:22 (GHPO 419),  
SEQ ID NO:24 (GHPO 431), SEQ ID NO:26 (GHPO 474), SEQ ID NO:28 (GHPO  
591), SEQ ID NO:30 (GHPO 596), SEQ ID NO:32 (GHPO 699), SEQ ID NO:34  
(GHPO 724), SEQ ID NO:36 (GHPO 730), SEQ ID NO:38 (GHPO 761), SEQ ID  
NO:40 (GHPO 804), SEQ ID NO:42 (GHPO 805), SEQ ID NO:44 (GHPO 812), SEQ  
ID NO:46 (GHPO 879), SEQ ID NO:48 (GHPO 888), SEQ ID NO:50 (GHPO 986),  
SEQ ID NO:52 (GHPO 1056), SEQ ID NO:54 (GHPO 1081), SEQ ID NO:56 (GHPO

1100), SEQ ID NO:58 (GHPO 1140), SEQ ID NO:60 (GHPO 1148), SEQ ID NO:62 (GHPO 1200), SEQ ID NO:64 (GHPO 1212), SEQ ID NO:66 (GHPO 1258), SEQ ID NO:68 (GHPO 1263), SEQ ID NO:70 (GHPO 1273), SEQ ID NO:72 (GHPO 1284), SEQ ID NO:74 (GHPO 1299), SEQ ID NO:76 (GHPO 1327), SEQ ID NO:78 (GHPO 1346), SEQ ID NO:80 (GHPO 1378), SEQ ID NO:82 (GHPO 1412), SEQ ID NO:84 (GHPO 1443), SEQ ID NO:86 (GHPO 1466), SEQ ID NO:88 (GHPO 1476), SEQ ID NO:90 (GHPO 1536), SEQ ID NO:92 (GHPO 1559), SEQ ID NO:94 (GHPO 427), SEQ ID NO:96 (GHPO 1045), and SEQ ID NO:98 (GHPO 1262); or

(ii) a derivative of said polypeptide.

44. A method of preventing or treating *Helicobacter* infection in a mammal, said method comprising administering to said mammal a prophylactically or therapeutically effective amount of a compound of claim 43.

45. The method of claim 44, further comprising administering an antibiotic, an antisecretory agent, a bismuth salt, or a combination thereof.

46. The method of claim 44, which further comprises administering a prophylactically or therapeutically effective amount of a second *Helicobacter* polypeptide or a derivative thereof.

47. The method of claim 46, wherein the second Helicobacter polypeptide is a Helicobacter urease, a subunit, or a derivative thereof.

48. A composition comprising a compound of claim 43, together with a physiologically acceptable diluent or carrier.

49. The composition of claim 48, further comprising an adjuvant.

50. The composition of claim 48, further comprising a second Helicobacter polypeptide or a derivative thereof.

51. The composition of claim 50, wherein said second Helicobacter polypeptide is a Helicobacter urease, or a subunit or a derivative thereof.

52. A method of preventing or treating Helicobacter infection in a mammal, said method comprising administering to said mammal a prophylactically or therapeutically effective amount of a polynucleotide of claim 39.

53. A composition comprising a viral vector, in the genome of which is inserted a DNA molecule of claim 40, said DNA molecule being placed under conditions for

expression in a mammalian cell and said viral vector being admixed with a physiologically acceptable diluent or carrier.

54. A composition that comprises a bacterial vector comprising a DNA molecule of claim 40, said DNA molecule being placed under conditions for expression and said bacterial vector being admixed with a physiologically acceptable diluent or carrier.

55. A composition comprising a polynucleotide of claim 39, together with a physiologically acceptable diluent or carrier.

56. An expression cassette comprising a DNA molecule of claim 40, said DNA molecule being placed under conditions for expression in a procaryotic or eucaryotic cell.

57. A process for producing a compound of claim 43, which comprises culturing a procaryotic or eucaryotic cell transformed or transfected with an expression cassette comprising a polynucleotide encoding said compound, and recovering said compound from the cell culture.

58. A method of preventing or treating Helicobacter infection in a mammal, said method comprising administering to said mammal a prophylactically or therapeutically

effective amount of an antibody that binds to the compound of claim 43.

### CONCLUSION

Applicants submit that the amendments set forth above place the claims in condition for allowance, which action is requested. If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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